

## **REMARKS**

Claims 1-30 are currently pending. Claim 1 has been amended. Claims 3 and 17-30 have been canceled. Claims 11-16 are withdrawn. Claims 31 and 32 have been added. No new matter has been added. On entry of these amendments, claims 1-2, and 4-16 will be pending in this application.

### **Election of Claims**

The Applicants affirm the election of Group I (i.e., claims 1-10 and 17-24) for further prosecution made during a telephone conversation with David McKone on March 2, 2010. Accordingly, claims 11-16 have been withdrawn from further consideration by this amendment and claims 25-30 have been canceled.

### **Amendments to Drawings**

The Applicants have submitted herewith a replacement sheet of drawings for Figures 4a-4c, which merely address typographical errors. The originally-filed Figures 4a-4b included a typographical error in that the horizontal axis included points  $t_0$  to  $t_4$  but should have included points  $t_0$  to  $t_5$  as shown in Figure 4c and described in paragraphs [0034]-[0035] of the Present Application. The replacement sheet of drawings addresses only these typographical errors. Accordingly, no new matter has been added by this amendment.

### **Obvious-Type Double Patenting**

Claims 1, 2, 5-10, 17, 18 and 20-24 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Pat. No. 6,841,052 (the ‘052 Patent). The Applicants have amended independent claim 1 to include the subject matter of dependent claim 3. Claim 3 of the Present Application is not alleged to be unpatentable over claims 1 and 2 of the ‘052 Patent. Accordingly, the amendments to independent claim 1 renders the double patenting rejection of claims 1, 2, and 5-10 moot. Claims 17, 18 and 20-24 have been canceled. The Applicants respectfully request withdrawal of the rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

### **Claim Rejections - 35 U.S.C. § 112**

Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. While the Applicants disagree with this rejection, claim 17 has been canceled by this amendment in the interest of expediting prosecution. Accordingly, the rejection under 35 U.S.C. § 112, second paragraph, is moot.

### **Claim Rejections – 35 U.S.C. §§ 102, 103**

#### ***Amended Independent Claim 1***

Amended independent claim 1 recites, *inter alia*, “the high-resistance portion including a resistor.” European Publ. No. 1074832 A1 (Musho) is acknowledged not to disclose or suggest the claimed resistor. See Office Action, page 9. In an attempt to address this deficiency, the Office Action applies U.S. Pat. No. 6,814,844 (Bhullar) as allegedly teaching “screen-printed carbon can be utilized in order to limit current/direct current flow.” Office Action, pages 9-10. The Office Action concludes that “it would have been obvious to one skilled in the art to modify the counter electrode of Musho by incorporating a screen-printed carbon patter (i.e. resistor) as taught by Bhullar et al. because the carbon layer will act as a resistor and direct current/limit current flow to particular parts of the circuit and in contrasting the electrical conductivity when one or both of the high and low resistance portions of the counter electrode are covered in fluid.” Office Action, page 10.

Obviousness requires a teaching that all elements of the claimed invention are found in the prior art and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does” *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007); *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (“Rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”). The Applicants respectfully submit that the alleged reason for modifying Musho in view of Bhullar lacks a rational underpinning to support a *prima facie* finding of obviousness under 35 U.S.C. § 103 for at least the reasons stated below. Because the Office Action fails to set forth a *prima facie* case

of obviousness, the burden to rebut this rejection has not yet shifted to the Applicants. MPEP § 2145.

#### I. The Office Action Mischaracterizes the Teachings of Bhullar

The alleged reason for modifying Musho in view of Bhullar lacks a rational underpinning because the Office Action mischaracterizes the teachings of Bhullar. In particular, Bhullar does not teach a “carbon layer will act as a resistor and *direct current/limit current flow to particular parts of the circuit*” as alleged in the Office Action. Office Action, page 10 (emphasis added). Rather, Bhullar merely teaches that a variety of materials (e.g., the alleged carbon layer) can be coated on a substrate to achieve an electrically readable *coded pattern*. Bhullar, col. 4, lines 1-11. In particular, Bhullar discloses that a substrate is coated with an electrically conductive material and then portions of the electrically conductive material are removed to form a coded pattern defined by a contrast in conductivity between the portions covered in conductive material and the portions that have been removed. See, e.g., Bhullar, col. 1, lines 38-46. The code pattern may identify an individual biosensor or a set of calibration data for the biosensor. Bhullar, col. 4, lines 38-46.

Significantly, Bhullar does not disclose or suggest in any way how the coded pattern “directs current/limits current flow to particular parts of the circuit.” Rather, Bhullar expressly discloses that “the code pattern 40 is isolated from the rest of the electrically conductive material 13 on substrate 12 by gaps 42.” Bhullar, col. 4, lines 25-27; FIG. 4. Accordingly, the code pattern 40 does not direct current or limit current to any part of any circuit on the Bhullar biosensor. Instead, the coded pattern on the sensor is read by a pattern reader on a meter. Bhullar, col. 7, lines 3-4.

Therefore, the alleged reason for modifying Musho in view of Bhullar is based on an mischaracterization of the teachings of Bhullar and, thus, is improper. Therefore, one skilled in the art would not be motivated by the coded pattern teachings of Bhullar to modify Musho to include a resistor for detecting an under-filled condition.

The Office Action has further applied U.S. Pat. No. 5,620,579 (Genshaw). Genshaw does not address the deficiencies discussed above.

For at least these reasons alone, the Office Action failed to set forth a *prima facie* case of obviousness over Musho, Bhullar, Genshaw or any combination thereof, and the Applicants respectfully request withdrawal of this rejection.

II. There is no Rational Reason to Modify Musho to Include a Resistor

Additionally, a person of ordinary skill in the art also would not have modified Musho to include a resistor because it would have been completely unnecessary. Musho discloses a sensor that includes a counter electrode having a major portion 40b and a sub-element 40a, which is smaller in size and located upstream from the major portion 40b of the counter electrode. Musho, col. 4, lines 9-21. During an under-filled condition, the sub-element 40a is the only portion of the counter electrode that is contacted by the sample fluid. Musho, col. 4, lines 9-27. Musho discloses that it is important that the reagent layer does not contact the sub-element 40a to prevent it from functioning “as a proper reference electrode, so that an error condition is achieved.” Musho, col. 4, lines 33-42. In other words, because of the small size of sub-element and because the reagent does not contact the sub-element 40a, only a small amount of current will flow through the sub-element 40a during an under-filled condition. *Id.* This low current is distinguishable from the current passing through the major portion of the counter electrode 40b, which is contacted by the reagent.

Because the difference in currents is generated as a result of area of the sub-element and the isolation of the sub-element from the reagent, it would not have been necessary to have a resistor. Stated differently, the reason for modifying Musho set forth in the Office Action lacks a rational underpinning because the objective of the alleged modification to Musho (i.e., to generate distinct currents) is already achieved by the sensor disclosed by Musho. There is simply no express or implied suggestion to modify Musho to include a resistor as alleged in the Office Action.

For at least these reasons alone, the Office Action failed to set forth a *prima facie* case of obviousness over Musho, Bhullar, Genshaw or any combination thereof. Accordingly, the Applicants respectfully request withdrawal of this rejection.

***Dependent Claims 2, 4-10, and 31-32***

Claims 2, 4-10, and 31-32 depend directly or indirectly from independent claim 1. For at least this reason, the Office Action failed to set forth a *prima facie* case of obviousness for claims 2, 4-10, and 31-32. Accordingly, the Applicants request withdrawal of the rejection of claims 2, 4-10, and 31-32.

**Conclusion**

The Applicants submit that the claims are in a condition for allowance and action toward that end is earnestly solicited. Pursuant to 37 C.F.R. § 1.17(a)(1), the Commissioner is authorized to deduct the extension fees of \$130. It is believed that no additional fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Nixon Peabody LLP Deposit Account No. 50-4181, Order No. 247082-00117USPX.

Respectfully submitted,

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